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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,952	03/22/2002	Stephen H. Leppla	15280-4051US	4741

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/088,952

Applicant(s)

LEPPLA ET AL.

Examiner

Brandon J. Fetterolf, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-29 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,6,10,15-17,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,9,11-14,18-22 and 25-29 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Leppla et al.

***Response to the Amendment***

The Amendment filed on 06/16/2005 in response to the previous Non-Final Office Action (12/15/2004) is acknowledged and has been entered.

Claims 1-4 and 6-29 are currently pending.

Claims 2-3, 6, 10, 15-16 and 23-24 are withdrawn from consideration as being drawn to non-elected inventions.

Claim 17 has been withdrawn from consideration by Applicants.

Claims 1, 5, 7-9, 11-14, 18-22 and 25-29 are currently under consideration.

Note: In the original Office Action of 12/15/2005, Claim 17 was examined along with the claims that are currently under consideration. However, it appears that Applicants have withdrawn Claim 17.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 1, 4-5, 8, 11-14, 18-22 and 25-29 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Leppla et al. (IDS, 1997) in view of Bayley *et al.* (IDS, 1998) for the reasons of record in the prior Office Action (12/15/2004, pages 6-8) and for the reasons set forth below.

In reference to the previous action which held that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to incorporate a plasminogen activator-protease cleavage site in place of the native protective antigen furin-recognized cleavage site as a way of targeting a compound to a cancer cell over-expressing a plasminogen activator or plasminogen activator receptor, Applicant's assert (Page 8) that the as set forth in the M.P.E.P. 2143,

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“[t]o establish a prima facie case of obviousness, three criteria must be met: (1) there must be some suggestion or motivation, wither in the reference themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all of the limitations. Moreover, Applicants argue that as set forth in U.S.C. 103(c), and clarified in MPEP 706.02 (1)(2)(I), (c) subject matter ... which qualifies as prior art only under one or more subsections (e), (f), and (g) of section 102 of this title, shall **not** preclude patentability where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (emphasis added) Applicants note that both the instant application and Leppla et al. were, at the time the invention was made, both owned by and subject to an obligation of assignment to the same person, i.e., the Government of the United States as Represented by the Secretary of the Department of Health and Human services; and therefore, is not a reference that is properly cited against the instant application.

These arguments have been considered, but are not found persuasive.

First, the previous rejection was based on the technical reasoning that necessarily flowed from the teachings of the prior art- Leppla et al. teach a method for targeting compounds having a desired biological activity not present on native anthrax lethal factor (LF) to a specific cell population, while Bayley et al. teach the incorporation of a protease cleavage site from a plasminogen activator into a conjugate for specific activation of this cell type. Although Applicants point to the criteria (M.P.E.P. 2143) needed to establish a prima facie case of obviousness, Applicants have provided any arguments on why the combination of Leppla et al. and Bayley et al. do not meet the criteria set forth in M.P.E.P. 2143. In the instant case, Applicants primary argument appears to be that the Leppla et al. reference was improperly cited against the instant application because, as set forth in U.S.C. 103(c), and clarified in MPEP 706.02 (1)(2)(I), (c), the instant application and Leppla et al. were, at the time the invention was made, both owned by and subject to an obligation of assignment to the same person, i.e., the Government of the United States as Represented by the Secretary of the Department of Health and Human services. As stated by Applicants, the MPEP 706.02 (1)(2)(I), (c) and U.S.C. 103 (c) states that subject matter ... which qualifies as prior art only under one or more subsections (e), (f), and (g) of section 102 of this title,

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shall **not** preclude patentability where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (emphasis added) While the Examiner agrees with Applicants quotation of the MPEP 706.02 (1)(2)(I), (c), the Leppla et al. reference would qualify under subsection (b) of section 102 and not one or more subsections (e), (f), and (g) of section 102. In view of MPEP 706.02 (1)(2)(I), (c), it appears that the reference was properly cited against the instant application. Therefore, claims 1, 4-5, 8, 11-14, 18-22 and 25-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Leppla et al. (IDS, 1997) in view of Bayley *et al.* (IDS, 1998).

Note: Claim 7 is objected to as being dependent from rejected independent claim 1. In the instant case, the prior art does not appear to suggest that the plasminogen activator recognized cleavage site is SEQ IDNO: 5.

**All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.**

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**  
4/19/05